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Title: METHOD FOR MARKING, TRACKING, AND MANAGING HOSPITAL INSTRUMENTS

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## **BACKGROUND OF THE INVENTION**

### **1. Field of the Invention**

The present invention relates to a method for marking, tracking, and managing hospital instruments. Specifically, the present invention relates to a method for marking instruments with information indicative of the manufacturer, part number, serial number and manufacturing data of each instrument, inputting such information into a database, along with information regarding the desired maintenance schedule, and usage of each instrument, and tracking the usage and/or maintenance of each instrument by using the information in the database. The method also includes asset management, instrumentation identification and counting, and assembly of surgical trays and kits.

### **2. Description of the Prior Art**

It is extremely important to monitor and/or track the use of hospital instruments, particularly instruments used to perform surgery. Large hospitals often comprise many different departments. This multidepartment organizational structure frequently results in nonuniform, rather than centralized, attempts to track the maintenance and/or usage of hospital instruments.

Hospital instruments are expensive and often have short or limited useful lifetimes. The term "hospital instrument", as used herein refers to any

instrument or device used for patient care, diagnosis, therapy, or surgery in a hospital or in the office of a physician or surgeon. By way of example, hospital instruments may include, but are not limited to, defibrillators, ultrasonography transducers, and surgical instruments such as forceps. The  
5 term "hospital procedure", as used herein, refers to any procedure performed in a hospital or in the office of a physician or surgeon, using a hospital instrument. By way of example, hospital procedures include, but are not limited to, surgery, defibrillation, ultrasound imaging, and magnetic resonance imaging. The costs associated with maintaining and/or replacing hospital  
10 instruments are relatively high.

The lack of a centralized system for marking, tracking, and managing hospital instruments can result in unnecessary replacement costs, higher than necessary inventory levels, the failure to perform needed maintenance in a timely manner, or increased exposure to liability resulting from insufficient  
15 documentation of maintenance practices. The present invention overcomes the drawbacks of the prior art by providing a centralized system and/or method for marking, tracking, and managing hospital instruments.

Other prior art methods for marking surgical instruments require two separate marking techniques, one technique for surgical instruments having a mirror finish and a second technique for surgical instruments having a nonmirror finish. Such a method is disclosed in U.S. Patent No. 5,637,850 to  
20 Honda. Such dual marking methods are expensive in that they require complex hardware and software capable of distinguishing between the two different types of marking techniques used for different finishes on surgical  
25 instruments.

The present invention provides a great advantage over such prior art methods in that a single marking technique is used, regardless of the finish on a hospital instrument. This single marking technique provides economy, not only in the hardware used to mark the hospital instruments, but also in the hardware and software used to read the marks.

### **SUMMARY OF THE INVENTION**

The present invention is directed toward a method for marking and tracking a multiplicity of hospital instruments. This method comprises marking at least two hospital instruments with an optically scannable mark indicative of each instrument's manufacturer or service provider and indicative of a serial number unique to each instrument. The invention also comprises reading each mark and entering serial number and manufacturer information represented by each mark into a computer database. The invention further comprises using one or more of the instruments to perform one or more hospital procedures and entering information into the database that identifies each hospital procedure in which each instrument has been used.

The present invention may also be used to identify the sterilization and maintenance on each hospital instrument, identify instrument replacement as required or performed, conduct training, and/or identify the number of usages, repairs, and/or complaints associated with each instrument.

### **DESCRIPTION OF THE DRAWINGS**

Figure 1 is a block diagram of a first embodiment of the present invention.

Figure 2 is a block diagram of a second embodiment of the present invention.

Figure 3 is a block diagram of a system suitable for practicing the methods of the present invention.

Figure 4a is a side view of the marking step of the present invention.

Figure 4b is a side view of the scanning and entering step of the present invention.

Figures 5a-5b are a block diagram of a third embodiment of the present invention.

### DESCRIPTION OF THE PREFERRED EMBODIMENTS

A first embodiment of the present invention is directed toward a method for marking and tracking a multiplicity of hospital instruments. This embodiment comprises marking at least two hospital instruments with an optically scannable mark 35 indicative of each instrument's manufacturer and indicative of a serial number unique to each instrument, as shown in Block 10 of Figure 1 and in Figure 4a. In a preferred embodiment, the marking is performed with a laser 36, as shown in Figure 4a.

A suitable method for laser marking is laser etching. Laser etching can be used to mark coatings applied to the substrate of a hospital instrument. Pigments may be added to coatings on a hospital instrument in order to effect a color change when the pigments are subjected to a laser in the laser etching process. Suitable pigments for laser etching are available from Infosight Corporation of Chillicothe, Ohio.

Laser bonding is also a suitable method for laser marking many hospital instruments. Laser bonding is a process which involves the bonding of a material to a substrate surface using the heat generated by a laser. Pigments suitable for use with laser bonding are available from Cerdec Corporation of Washington, Pennsylvania. In other preferred embodiments, the marking is performed using an ink jet or an acid etch.

The laser marking technique may be laser etching, laser alloying or a combination of laser alloying and laser etching. Laser alloying may be

accomplished by coating the selected surface of the hospital instrument to be marked with a thin layer of precursor comprising metallic or ceramic elements suspended in a binder. The precursor coated instrument is then irradiated with a laser in a preselected pattern to form a patterned alloyed surface layer on the instrument. The selection of precursor elements will be a function of the chemical and/or materials composition of the hospital instrument. Alternatively, a selected surface area of the instrument may be irradiated to form a regional alloyed layer or apron. Other marking techniques, such as laser etching, may then be applied to the apron to produce a highly visible and wear resistant mark.

This embodiment of the invention further comprises reading each mark 35 and entering serial number and manufacturer information represented by each mark into a computer database 40 as shown in Block 12 of Figure 1 and in Figure 4b.

In a preferred embodiment, the reading and entering comprises scanning with an optical scanner 38 electrically coupled to the database 40. The optical scanner automatically cycles through various lighting schemes and lenses to optimize the image capture. A suitable scanner for use in practicing the present invention is the RVSI MX-1 Handheld Reader, available from RVSI of Canton, MA.

In another preferred embodiment, the optical scanner is portable, as shown in Figure 4b. The electrical coupling provides a data transfer path or link between the scanner and the database. The data may also be transferred from the scanner to the database via infrared data transmission methods well known in the art, including Infrared Data Association (IrDA) standards. Other methods of wireless data transfer known in the data communications arts may also be employed in practicing the data entry step of the present invention,

including but not limited to RF methods. Other methods of data entry may include voice recordation or terminal entry.

In a preferred embodiment, the database is a relational database. The term "relational database", as used herein, encompasses a database comprising multiple entries, wherein each entry comprises multiple fields of information. In the context of the present invention, it is envisioned that entries will be specific to each instrument. The fields of information on each entry may include manufacturer, part number, serial number, usage history, and/or maintenance history.

In a relational database, information can be stored, sorted, and/or received based upon specified relations between various fields for each entry. For instance, in a relational database for the present invention it will be possible to retrieve entries on all instruments from a specified manufacturer, used in a specific hospital procedure within a specified time period. Such search and retrieval capabilities will facilitate using the present invention to audit instrument maintenance programs. A suitable relational database for use in practicing the present invention is DeRoyal's Meridian Instrument Control System and Pathways Management Module. Another relational database suitable for use in practicing the present invention is the Access database available from Microsoft Corporation of Redmond, Washington.

In a preferred embodiment, the database is accessible at multiple data entry and retrieval locations or data terminals 42, as shown in Figure 3. In another preferred embodiment, the database is accessible in a computer network. The data terminals 42, shown in Figure 3 may also be computers. In such an embodiment, Figure 3 illustrates a simplified computer network.

This embodiment of the invention further comprises using one or more of the instruments to perform one or more hospital procedures, as shown in Block 14 of Figure 1. This embodiment of the invention further comprises entering information into the database that identifies each hospital procedure in which each instrument has been used, as shown in Block 16 of Figure 1.

A second embodiment of the present invention is shown in Figure 2. This embodiment is directed toward a method for marking, tracking, and maintaining a multiplicity of hospital instruments.

It comprises marking at least two hospital instruments with an optically scannable mark indicative of each instrument's manufacturer or service provider and part number, and indicative of a serial number unique to each instrument, as shown in Block 20 of Figure 2. The term "part number", as used herein, refers to a number unique to each species or type of instrument, such as each trocar or each scalpel. The part number may be used to designate instruments for specified groupings, such as groups of instruments for surgical or hospital kits.

This embodiment of the present invention also comprises reading each mark and entering part number, serial number, and manufacturer or service provider information conveyed by each mark into a computer database, as shown in Block 21 of Figure 2. In another preferred embodiment, the reading and entering is performed with a portable optical scanner 38 electrically coupled to the computer database, as shown in Figures 3 and 4b. The present invention may also be used to scan groups of instruments that are placed in a kit or to identify instruments for sorting into kits. The kit may also be marked, scanned and tracked using the present invention.

This embodiment of the present invention further comprises using one or more of the instruments to perform one or more hospital procedures as shown in Block **22** of Figure 2, and entering information into the database that identifies the serial number of each instrument and each hospital procedure in which it has been used, as shown in Block **23** of Figure 2. Hospital procedure information may include an identification of the specific procedure, when it was performed, the nurses/technicians assigned to the procedure, and the surgeons who performed it.

This embodiment of the present invention further comprises inputting a maintenance schedule for each instrument into the database as shown in Block **24** of Figure 2 and retrieving maintenance schedule information from the database as shown in Block **26** of Figure 2.

In a preferred embodiment, the retrieving is performed at a data terminal **42** electrically coupled to the database **40**, as shown in Figure 3. The data terminal may be remotely located from the database. The terminal and database may be located in different buildings or in different rooms of the same building.

This embodiment further comprises performing maintenance on each instrument according to the maintenance schedule entered into the database, as shown in Block **28** of Figure 2. In a preferred embodiment, the invention further comprises entering information into the database identifying the maintenance procedure performed on each instrument, as shown in Block **30** of Figure 2.

A third embodiment of the present invention is directed toward a method for marking, tracking, and maintaining a multiplicity of hospital instruments and for auditing instrument maintenance. The invention may also



be used for determining and tracking replacement requirements and ordering information related to instruments. Such information is particularly useful to a hospital's procurement, or a physician's/surgeon's procurement, office or department. The present invention allows for the selective retrieval of information relevant to determining what replacement instruments should be ordered.

This embodiment is depicted in Figures 5a-5b. This method comprises marking at least two hospital instruments with an optically scannable mark indicative of each instrument's manufacturer or service provider and part number, and indicative of a serial number unique to each instrument, as shown in Block 70 of Figure 5a. The invention further comprises reading each mark with an optical scanner, and transmitting part number, serial number and manufacturer information conveyed by each mark from the scanner to a computer database, as shown in Blocks 71 and 72 of Figure 5a.

The invention further comprises using one or more of the instruments to perform one or more hospital procedures, and entering information into the database that identifies the serial number of each instrument and each hospital procedure in which it has been used, as shown in Block 73 and 74 of Figure 5a.

The invention further comprises inputting a maintenance schedule for each instrument into a database, and retrieving maintenance schedule information from the database, as shown in Blocks 75 and 76 of Figure 5b.

The invention further comprises performing maintenance on one or more of the instruments, and entering information into the database identifying the maintenance procedure performed on each instrument, as shown in Blocks 77 and 78 of Figure 5b.

The invention also comprises retrieving maintenance history and schedule information on one or more instruments and determining whether scheduled maintenance has been performed in a timely manner on the instruments, as shown in Block 79 in Figure 5b. This retrieval may take place  
5 from a data terminal capable of transmitting data to and receiving data from the database. The terminal may be remotely located from the database and coupled to the database via various data retrieval and/or transfer mechanisms, including, but not limited to, a telephone line 55 or a wireless telecommunication connection comprising a wireless modem, as shown in  
10 Figure 3. This step of the invention provides a mechanism for auditing compliance with the scheduled maintenance program.

The determination of whether scheduled maintenance has been performed in a timely manner can be accomplished by comparing the maintenance schedule for a particular instrument to the maintenance history  
15 for the same instrument. The use of a relational database can facilitate the selective retrieval of information for such a comparison.

The foregoing disclosure and description of the invention are illustrative and explanatory. Various changes in the size, shape, and materials, as well as in the details of the illustrative embodiments may be made without  
20 departing from the spirit of the invention.